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The impact of European research ethics legislation on UK radiology research activity: a bibliometric analysis

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AIM: To determine whether there is evidence of a reduction in radiology research activity in the UK following the implementation of the European research ethics legislation, which came in to force in 2001 and has been widely criticised as an impediment to research.

MATERIALS AND METHODS: A bibliometric analysis was performed by searching PubMed for all first-author publications from UK departments of ''radiology'' or ''medical imaging'' between 1995 and 2007. Results were subcategorized into those papers published in the highest cited general radiology journals and by publication type: original research, reviews, and case reports.

RESULTS: From 1995 to 2007 the total number of publications rose by 6.5% from 137 to 146 with the increase occurring in non-general radiology journals. Original articles fell from 18 in 1995 to 12 in 2003, but then rose to 24 by 2007 (33% rise). This dip was paralleled by a fall and then recovery in case report publications. The most dramatic change has been in the number of review articles, which has increased more than eightfold from seven in 1995 to 65 in 2007 to become the most common form of publication.

CONCLUSION: The overall number of original scientific articles, published by first-author UK radiologists, has increased slightly over the last 12 years despite a temporary fall associated with the introduction of new research ethics legislation.

Introduction

Research Governance and Ethics bureaucracy has received bad press.[1,2] In 2000, The Department of Health established the Central Office for Research Ethics Committees (COREC). European research ethics legislation, was introduced in 2001 (Directive 2001/20/EC) and became part of UK law. In 2001, the Department of Health produced ''*Governance arrangements for research ethics committees*'' (GAfREC) and in 2004 regulations were introduced in ''*the medicines for human use (clinical trials) regulations*''. This law (directive 2001/20/EC) defined the structure of local research governance and ethics administrations. The process of applying for favourable opinions from local research governance and ethics committees is now time-consuming and, for many, daunting. This bureaucracy is seen by many clinicians as an impediment to research, particularly by junior members of staff and non-academic clinicians.[1–7] Repeated audits at our institution place local research ethics applications in the top three barriers to research for consultant grade clinicians (along with time and money). Few radiology trainees have, until recently, undertaken postgraduate research degrees and, therefore, led large-scale research projects. For many radiology trainees, research projects have had to be manageable enough to fit in between Fellowship examinations. A typical 3–6 months governance and ethics application might well result in a reduction in the number of trainees and clinical radiologists attempting original research. This might manifest as a drop in overall

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numbers of radiology publications or a move from original research to other publications that do not require a favourable opinion from an ethics committee, such as review papers. There is, to the best of the authors' knowledge, no evidence to suggest that the new research ethics legislation has had a deleterious effect on radiology research output.

Bibliometrics is the measurement of text and information and is most often used in libraries and information sciences, but has applications in other areas. Bibliometry has been used to study trends in scientific publications by medical specialty on both national and international scales by trawling publication databases, such as Medline and PubMed.[8–10] The aim of the present study was to describe trends in radiology publications and to determine whether there is evidence of a reduction in radiology research activity in the UK following the implementation of new ethics processes.

Materials and methods

This was a retrospective study of the number of first-author publications, from departments of radiology in the United Kingdom, cited on PubMed. Departments were identified by searching for the terms ''department of radiology'' or ''department of medical imaging,'' and ''UK''. The plural versions of each of these was also included (the plural version appears when more than one department is cited by the lead author, e.g., Departments of radiology and surgery). The total number of publications for each year between 1988 and 2007 was recorded, but only data after 1995 were included in the results as it became apparent that before this date the department of the lead author was not reliably recorded in PubMed. For each year further search terms were then added. Results were subcategorized into those articles published in the six highest cited general radiology journals: *Clinical Radiology*, *Radiology*, *American Journal of Roentgenology*, *RadioGraphics*, *European Radiology*, and the *British Journal of Radiology*. Using the ''Limits'' tab, case reports and reviews were identified and recorded. The number of original articles were defined as those articles returned after checking the following search categories: clinical trial, randomized control trial, meta-analysis, clinical trial phases I–IV, comparative study, technical report, validation studies, controlled clinical trial, evaluation study, and multicenter (sic) study.

Results

From 1995 to 2007 there was slight overall rise of 6.5% in the total number of first author UK radiology publications which increased from 137 to 146 (median 146). Within this time period there was a nadir of 120 papers published in 2003 followed by a sharp rise to peak of 201 in 2006 (Table 1). This major fluctuation in publication numbers from 2003 to 2006 took place in journals other than the top six general radiology journals (Fig. 1).

The number of publications in the top six journals varied from 61 to 102 (median 86) compared with all others, where numbers varied from 46 to 106 (median 60). The percentage of all publications in the top six radiology journals coming from first-author UK radiologists varied little from 1995 to 2007 with a median of 3.8% (range 2.4–4.4%).

Table 1 First-author UK publications by journal type and publication type from 1995–2007

First-author UK publications		Journal type			Publication type		
Year	Number	General radiology journals	Percent of all general radiology journal publications	Other journals	Original research	Review	Case reports
1995	137	91	4.4	46	18	7	60
1996	152	98	4.4	54	24	21	58
1997	152	102	4.3	50	21	24	61
1998	146	86	3.8	60	29	30	52
1999	170	102	4.4	68	30	27	61
2000	134	64	2.4	70	26	23	44
2001	126	76	3.3	50	22	26	48
2002	145	84	3.5	61	23	37	37
2003	120	61	2.6	59	12	34	36
2004	161	75	3.2	86	19	48	47
2005	189	91	3.7	98	43	43	54
2006	201	92	3.9	109	34	52	48
2007	146	86	3.9	60	24	65	58

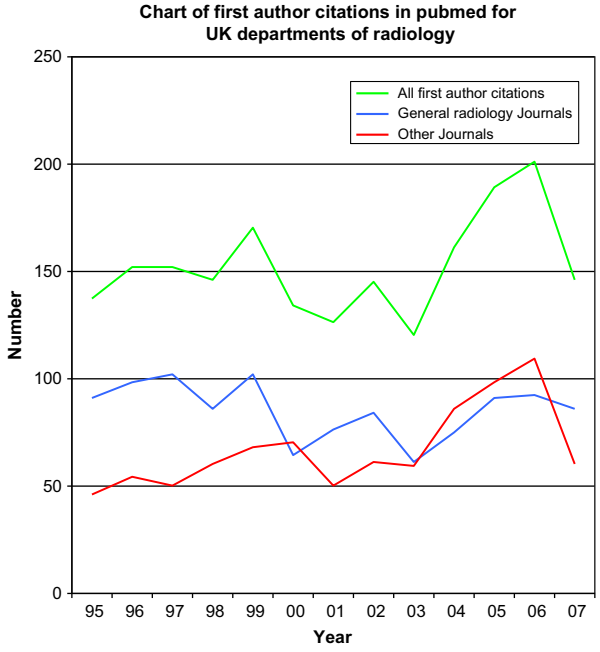

Figure 1 Chart of first-author citations in PubMed for UK departments of radiology.

In journals, other than the top six, numbers increased from approximately 50 per year in 1995 and 1996 to over 100 in 2006 (Fig. 1). In 2007, these citations appeared most commonly in three journals: *Cardiovascular and Interventional Radiology* ($n = 20$), *Skeletal Radiology* ($n = 18$) and *Paediatric Radiology* ($n = 9$). Other journals had three or less citations only in 2007 (Table 2).

The trough in overall publication numbers in 2003, which was then followed by a rise to a peak in 2006, appears to be determined by changes in the number of original articles and case reports (Fig. 2). The number of review papers has risen independent

Table 2 Journals published in 2007 other than the six main radiology journals with greater than one radiology research article

Journal title	Articles with a radiologist as first author (*n*)
Cardiovascular interventional radiology	20
Skeletal radiology	18
Paediatric radiology	9
Australasian radiology	3
Cancer imaging	3
European Journal of vascular and endovascular surgery	3
Emergency radiology	2
Thorax	2
AJNR American Journal of Neuroradiology	2
Emergency Medicine Journal	2
European Journal of Radiology	2
Journal of Ultrasound Medicine	2

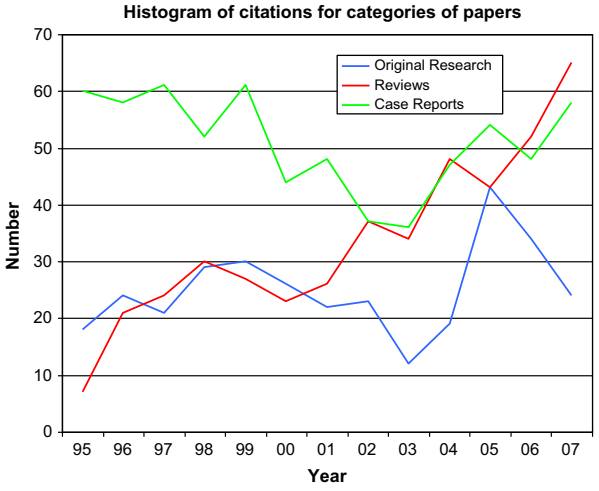

Figure 2 Histogram of citations for categories of papers.

of these overall trends. The number of original research articles published in 2007 is 33% higher than in 1995 with considerable variability in between (median 24, range 12—43). The number of cited case reports has changed little from 1995 to 2007 (60 to 58), but again demonstrates a trough with a minimum of 36 publications again in 2003. The most dramatic change has been in the number of review articles. These increased from seven in 1995 to 65 in 2007; an ninefold increase to become the most common form of publication in 2007.

Discussion

This study indicates a transient fall in publications by UK radiologists in 2003. Although it may be tempting to associate this trough with the start of ethics legislation in 2001, any association should be considered with caution. Any impact on the publication of original research requiring ethics approval is unlikely to be felt in less than 3 or 4 years. Twelve to 24 months for data collection, analysis and manuscript preparation followed by 12—18 months of manuscript submissions, revisions, and lead-time to publication is typical for research requiring Local Research Ethics Committee (LREC) approval. A proportion of the original research papers will not require LREC approval. These might include phantom studies, case series reports, and audits and, therefore, legislation will not have an impact on all activity classified as original research by the PubMed database. The concurrent dip in case reports suggests that there may also be other factors that affected output in 2003, which may include normal variation in activity, changes in activity from competing countries, or changes in editorial

policies. Based on these figures, there does not appear to be any evidence to support a claim that LREC legislation has adversely affected radiology research output in the UK.

Clinical radiology research has been burdened with separate ethics and Ionising Radiation (Medical Exposure) Regulations (IRMER) processes governing research with ionizing radiation, which unnecessarily increase the work associated with ethics applications. There have been some suggestions to resolve this excess bureaucracy[11] with moves to try and integrate COREC and IRMER and streamline the process.[12] There have been fears that this increased time and effort required getting research through governance and ethics processes has adversely affected research output in the UK. This study does not provide evidence to support this. Although numbers of British radiologists, consultants and trainees, have risen over the past 10 years, in the present data there is no evidence of a sustained increase in activity. This does not compare favourably with trends in the rest of Europe where there appears to be have been an increase in activity over a similar time period.[10,11] It has, until recently, been uncommon for radiology trainees to undertake research degrees in the UK, particularly when compared with their peers in medical and surgical training posts. This has been attributed to the fact that radiology trainees have to spend considerable time working for the FRCR, mid-way through their training, having already passed MRCP or MRCS/FRCS prior to entry in to radiology. In Poland and Austria, radiologists take their exams at the end of their training. In France there are no radiological examinations and German trainees undertake only a short oral exam, with variable content, depending on their training centre.[13] This variety allows trainees in one country more time for research than others, so that increases in trainee numbers in the UK may not lead to increasing research activity. At consultant level two things have happened recently that could contribute to a lack of growth in research. The first is a decline in numbers of academic radiologists in the UK.[14] The reason for this is uncertain, but numbers have always been relatively small with most publications coming from NHS consultants and, therefore, any drop in university consultants is unlikely to have had a large effect on publication rates. The new consultant contract, new appraisal, and job planning processes may have reduced the amount of supporting activity available to consultants for research activity, but this would be very difficult to confirm and is, therefore, speculative.

There are a number of limitations to the bibliometric data in this study. The results of this study can describe publication trends only. These do not necessarily represent research activity. First-author radiology publications represent a fraction of all published research that includes a radiologist as an author. One would have to assume that this ratio of first-author publications to other multi-author papers remained constant for this data to parallel research activity. The amount of effort required to write a review paper or a case report has probably not changed over the years and, therefore, the rise in number of published review articles probably does represent a change in activity in this field. However, the same can not be said for original research articles. A randomized, controlled trial may take 4 or 5 years to complete and may require hundreds of thousands of pounds of hard-won funding. In comparison a retrospective case series review can be completed relatively quickly and cheaply. Both will score the same single publication on PubMed. Therefore, although the numbers of first-author publications may not have changed substantially over the period of this study, it is possible that the intensity of research activity has changed. The metadata used to classify types of original research articles is not standardized between all journals and, therefore, categorical analysis of PubMed data is likely to be imperfect and, of course, still may not represent research activity accurately. The search criteria used in this study also limit publications to radiologists working in ''departments of radiology'' or ''medical imaging,'' thus, excluding many in specialist centres or those working in departments with non-standard titles. Again to be meaningful the proportion of these cases excluded from the search has to be assumed to be constant from year to year.

Despite these limitations, there are no other national databases for radiological research activity and, therefore, these data are probably, for the moment, the best glimpse of national activity available. As in other subspecialty areas bibliometric analysis offers a relatively easily acquired measure of activity, albeit one that needs to be interpreted with caution.

In conclusion, bibliometric analysis of first-author radiology publications provides no evidence to support a claim that ethics legislation has had a deleterious effect on radiology research activity in the UK. The overall number of original scientific articles, published by first-author UK radiologists, has increased slightly over the 13 years from 1995 to 2007. There has also been a dramatic ninefold

increase in the number of review articles published over the same period.

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